Appl. No. 09/944,896 Amdmt. dated February 17, 2005 Reply to Office Action of November 17, 2004

### **REMARKS**

#### In the Claims:

Claims 25-26 are cancelled herein without disclaimer or prejudice to pursuing the inventions of claims 25 and 26 in a continuing application.

Claims 27-35 and 38-41 are currently pending.

Claims 32-34 are currently allowed.

Amendment of claims 27 and 35 relates to form and/or grammar and is made only for the purpose of increasing the clarity of these claims. No new matter is added by these amendments.

Claim 38 is amended herein such that it no longer depends from rejected claim 25 but now depends from allowed claim 32. No new matter is added by this amendment.

## 35 U.S.C. § 112, second paragraph

Claim 35 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants thank the Examiner for kindly acknowledging that this rejection could be overcome by including the wash conditions of part (iii) of claim 35 in parts (i) and (ii). Applicants have amended claim 35 per the Examiner's kind suggestion. Thus, Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

# 35 U.S.C. § 112, first paragraph

#### **Enablement**

Claims 27, 34, 35, and 38-41 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Applicants thank the Examiner for kindly acknowledging that this rejection could be overcome by submission of an affidavit or declaration stating that "the deposit shall be made for a term of at least thirty (30)

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years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit that was received by the depository. Please find attached hereto as Exhibit A, a declaration to this effect executed by Bonny G. Yeung, Ph. D., of Genentech, Inc. Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

## **Written Description**

Claims 25-31, 35, and 38-41 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement.

### Claims 38-41:

Applicants have herein amended claim 38 such that it no longer depends from rejected claim 25, but now depends from allowed claim 32. Claims 39-41 depend from claim 38. Applicants respectfully submit that amendment of the dependency of claim 38 overcomes the rejection of claims 38-41. Therefore, Applicants respectfully request that this ground of rejection be withdrawn for claims 38-41.

### Claims 27-31, 35:

As the Office action states, claims 27-31 "encompass a nucleic acid which encodes the polypeptide of SEQ ID NO:50." The Office action further states that claims 27-31 encompass naturally occurring allelic variants. According to the Office action, the combination of sequence identity to a particular sequence and the functional characteristic of being amplified in a lung or colon tumor does not provide adequate written description for the sequences because one could not predict what such naturally occurring sequences would look like. Applicants respectfully disagree.

Applicants have fully disclosed the amino acid sequence of PRO347 in SEQ ID NO:50. Thus, Applicants are in possession of and have adequately described all nucleic acids encoding SEQ ID NO:50, as recognized by the United States Court of Appeals for the Federal Circuit in *In re Wallach*, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004). Specifically, in *Wallach*, the Federal Circuit recognized that "the state of the art has developed such

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that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it." *In re Wallach*, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004). Indeed, "[a] claim to the genus of DNA molecules complementary to [a known] RNA [sequence], even if defined only in terms of the protein sequence that the DNA molecules encode, while containing a large number of species, is definite in scope and provides the public notice required of patent applicants." *Id.* 

The MPEP also takes this approach at §2163.II.A.3.a.ii:

Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

Thus, the allelic variants encompassed by claims 27-31 are adequately described because "[g]iven the amino acid sequence, one can determine the chemical structure of all nucleic acid molecules that can serve the function of encoding that sequence." Wallach, 71 USPQ2d at 1943.

Moreover, as the Office action acknowledges, based on Applicants' descriptions set forth at pages 122-137 of the specification, one of skill in the art would know how to screen and isolate sequences with the functional characteristic of being amplified in lung or colon tumors. Thus, Applicants respectfully submit that claims 27-31, and 35, which encompass a nucleic acid which encodes or hybridizes to the polypeptide of SEQ ID NO:50, are adequately described by the combination of description and possession of a genus of nucleic acids encoding a fully disclosed protein sequence and a description of how to screen and isolate sequences with the functional characteristic of being amplified in lung or colon tumors. Applicants have overcome this ground of rejection for claims 27-31, and 35 and respectfully request that it be withdrawn.

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## Claims 25-26:

Claims 25 and 26 are cancelled herein without disclaimer or prejudice to pursuing the inventions of claims 25 and 26 in a continuing application. Therefore, Applicants have overcome this ground of rejection and respectfully request that it be withdrawn.

#### SUMMARY

Applicants believe that currently pending Claims 27-35 and 38-41 are patentable. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite allowance of this application.

Respectfully submitted,

C. Noel Kaman

Registration No. 51,857 Attorney for Applicants

C. Neel Karnan

BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, ILLINOIS 60610 (312) 321-4200 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of

Botstein et al.

Serial No. 09/944,896

Filed: A

August 31, 2001

Title: SECRETED AND TRANSMEMBRANE

POLYPEPTIDES AND NUCLEIC ACIDS ENCODING THE SAME

Examiner: Eileen B. O'Hara

Group Art Unit: 1646

The Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

# **DECLARATION PURSUANT TO 37 CFR 1.808**

Dear Sir:

I hereby aver that the nucleic acid of SEQ ID NO:49, which encodes the protein of SEQ ID NO:50, was deposited with the American Type Culture Collection (ATCC) December 10, 1997 and was given ATCC deposit number 209532. Accordingly, the deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the deposit of Microorganisms for the Purposes of Patent Procedure and all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of the patent.

The deposited material is identical to the biological material and was in the Applicant's possession at the time the application was filed. The deposit shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the fumishing of a sample of the deposit was received by the depository.

GENENTECH, INC.

Date: February 17, 2005

Bonny G. Yeung, Ph.D.

Title: Patent Agent